

Appln No.: 09/996,128
Amendment Dated: May 1, 2006
Reply to Office Action of November 1, 2005

REMARKS/ARGUMENTS

This is in response to the Office Action mailed May 6, 2005 for the above-captioned application. Reconsideration and further examination are respectfully requested.

Applicants request an extension of time sufficient to make this response timely and enclose the fee.

The Examiner also provisionally rejected claims 1-6, 10-13 and 28 for obviousness type double patenting in view of Application Serial No. 10/041,410. Applicants had previously indicated that they would file a terminal disclaimer if it is appropriate when an indication of allowability is received. Applicants now realize, however, that this would not be possible because this application and the prior application are not commonly assigned due to additional disclosure, including the application to canine malignant melanoma (claim 20). Accordingly, Applicants have in this application canceled claims 1-19, such that only claims that are not subject to the double patenting rejection remain. This amendment is made without prejudice to the right to file a continuation application with respect to the canceled claims.

The Examiner objected to claim 29 asserting that they contain non-elected subject matter, and states that correction is required. Applicants point out, however, that these claims are linked to the elected claims via generic claim 20. Accordingly, no amendment is reasonably required at this time since on allowance of the generic claim, these species would have to be considered.

Claims 30 has been added dependent on claim 20. This amendment is supported in the paragraph bridging pages 4 and 5. The statement that the vector is non-viral is made to clarify that the claim is referring to the non-viral alternative expressed in this paragraph.

The Examiner maintained the rejection of claims 20, 21, 23 and 29 under 35 USC § 112, first paragraph for lack of enablement. The Examiner acknowledges enablement of the method where the xenogeneic differentiation antigen is human tyrosinase or human gp75. With respect to other types of subjects, or other differentiation antigens, however, the Examiner asserts based on several general references¹ that there is a lack of enablement. Applicants respectfully disagree.

¹ It is noted that the Examiner has not provided copies, nor a form PTO-892 with respect to the Verma, Anderson, Miller, Deonarian, or Crystal references, and therefore Applicants submit that these are not properly of record. Applicants request copies of the reference and an 892 be placed in the record, even if the rejection is not maintained.

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The Examiner states on Pages 5 and 6 of the official action that

The specification provides guidance as to how to target the administered human tyrosinase nucleic acids to the non-human dog subjects and human gp75 to non-human subject. However the instant specification does not teach how to overcome the problems of *in vivo* delivery and expression with respect to the broad genus of differentiation antigens claimed.

The "problems" referred to in this paragraph are presumably those referred to in the generalized references cited by the Examiner. However, the Examiner has not offered any reasons why a person skilled in the art would doubt that the same methods of administration used in the animal species of the examples would not be effective in other mammalian species. Thus, Applicants submit that the Examiner has failed to present a valid basis for an enablement rejection as it relates to other species.

As observed previously, *In re Marzocchi*, 169 USPQ 367 (CCPA 1971) states that

a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112, *unless* there is a reason to doubt the objective truth of the statements contained therein, which must be relied upon for an enabling disclosure.

This objective doubt must be based on all of the evidence in the record, including the manner in which the statements and examples of the application would be understood by a person skilled in the art. In this case, because the Examiner has not indicated **why** a person skilled in the art would have doubt as to the ability to use xenogeneic tyrosinase or gp75 derived from other species or other types of melanoma-related differentiation antigens, the Examiner's reliance on the generalized references is insufficient to meet this burden.

It is noted that the Examiner still focuses on "gene therapy" and delivery to a "target" cell population in a manner that is not relevant to the present invention. The Examiner states that the references show in the context of gene therapy, the problems have been an inability to deliver genes efficiently and to sustain expression, and also raise issues with regulation. As previously observed, the field of gene therapy is much broader than genetic immunization which is what the present application relates to. The Examiner has not explained, why a person skilled in the art would find it unbelievable that the same delivery system that works for immunization with tyrosinase and gp75 would work for immunization with other melanoma-associated differentiation antigens. Further, in the context of stimulating an immune response, the notion of

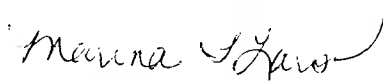
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sustained expression is irrelevant. This is not an instance of providing a replacement protein where the benefits are obtained only for so long as the replacement protein is expressed. This invention relates to an immunization, and it is standard practice in immunizations to provide only a short exposure to the immunogenic antigen.

Thus, Applicants again submit that the rejection for lack of enablement is in error and should be withdrawn. Furthermore, Applicants request clarification as to why the res

The Examiner rejected some of the canceled claims as anticipated by or obvious over, Zhai et al, alone or in combination with US Patent No. 5,773,291. These rejections are rendered moot by the cancellation of the rejected claims.

Respectfully submitted,



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Enclosures